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Amendment and Response

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Serial No.: 10/019,643

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Filed: March 20, 2002

For: METHOD AND COMPOSITION FOR AFFECTING REPRODUCTIVE SYSTEMS

REMARKS

The Office Action mailed September 26, 2006, has been received and reviewed. Claims 6 and 29 having been amended and claims 1-3, 5, 7-11, 16, 20, 22-26, and 30-41 having been canceled, the pending claims are claims 4, 6, 12-15, 17-19, 21, 27-29 and 42-47. Reconsideration and withdrawal of the rejections are respectfully requested.

Piecemeal Prosecution

MPEP 707.07(g) directs that "piecemeal examination should be avoided as much as possible." Further, "[w]hen an examiner is assigned to act on an application which has received one or more actions by some other examiner, full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general the second examiner should not take an entirely new approach to the application or attempt to reorient the point of view of the previous examiner, or make a new search in the mere hope of finding something" (MPEP 704.10 and 706.04).

Briefly, a first Office Action on the merits was mailed July 14, 2003, rejecting the claims as anticipated under 35 U.S.C. §102(b). This was followed by a nonfinal Office Action, mailed January 16, 2004, identifying the claims as allowable, except for an objection to claim 16, for an informality. In the next nonfinal Office Action mailed May 5, 2004, *the Examiner acknowledged that the claims are "enabled for the treating a reproductive disease that is related to egg laying or fertilization,"* however, the claims are not enabled "for treating neoplasia of the reproductive tract or cystic hyperplasia" (see page 2, Office Action mailed May 5, 2004) and the claims were rejected under 35 U.S.C. §112, first paragraph. This was followed by Office Actions mailed September 22, 2004, March 4, 2005, May 18, 2005, October 21, 2005, February 22, 2006, April 13, 2006, and most recently, September 26, 2006. In the nonfinal Office Action mailed April 13, 2006, the claims were newly rejected under 35 U.S.C. §102 and §103. With the present nonfinal Office Action, mailed September 26, 2006, these rejections

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were withdrawn and replaced with new rejections under 35 U.S.C. §103, 35 U.S.C. §112, second paragraph, and 35 U.S.C. §112, first paragraph, as not enabled. Applicants note that the recitations rejected to under 35 U.S.C. §112, second paragraph, have, in most cases, been present in the claims since the early stages of prosecution, if not present in the claims as originally files.

Applicants express considerable concern with the apparent incremental, piecemeal prosecution of the present application and the added prosecution costs and time delays associated with such piecemeal prosecution.

The 35 U.S.C. §112 Rejection, second paragraph

The Examiner has newly rejected claims 4, 6, 12-15, 17, 18, 21, 28, 29, and 42-47 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner asserted that the recitation "related to" egg production or egg laying is unclear. Applicants disagree. Read in full context, claim 4 is drawn to "a method for treating or preventing a reproductive disease, disorder, or condition related to egg production or egg laying in a bird. Applicants submit that reproductive diseases, disorders, or conditions "related to" egg production and egg laying in a birds are well understood to one of ordinary skill in the art, that is the veterinary care and husbandry of birds. Further, Applicants direct the Examiner to dependent claim 6, which provides a representative listing of reproductive diseases, disorders, or conditions related to egg production or egg laying in birds. Finally, Applicants express concern that the present Examiner, newly assigned to the application, is failing to give "full faith and credit . . . to the search and action of the previous examiner" and that the present application is being subjected to piecemeal prosecution (see MPEP 704.10 an 706.04).

Applicants direct the Examiner to the Office Action mailed May 5, 2004, in which the Examiner rejected claims 4, 6, 12-21, 23, and 27-29 under 35 USC § 112, first paragraph, stating that "the specification, while being enabling for treating a reproductive disease that is *related to* egg laying or fertilization, does not reasonably provide enablement for treating neoplasia of the reproductive

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tract or cystic dysplasia" (see page 2 of Office Action mailed May 5, 2004). In the Amendment and Response filed March 16, 2005, claim 4 was amended to recite "method for treating or preventing a reproductive disease, disorder, or condition related to egg production or egg laying in a bird" and the rejection of claims 4, 6, 12-21, 23, and 27-29 under 35 USC § 112, first paragraph, was withdrawn (see Office Action mailed May 18, 2005). This Office Action (mailed May 18, 2005) and subsequent Office Actions (mailed October 21, 2005, February 22, 2005, and April 13, 2006) found nothing objectionable under 35 USC § 112, second paragraph, with the recitation "method for treating or preventing a reproductive disease, disorder, or condition related to egg production or egg laying in a bird." Reconsideration and withdrawal of this rejection is requested.

Further, the Examiner asserted that the recitation "cloacal problems" in claim 6 was indefinite. While Applicants disagree, to expedite prosecution, claim 6 has been amended to remove this recitation. Applicants submit that this rejection is overcome in view of this amendment to claim 6.

The Examiner asserted that the recitation "undesireable behavior as a result of reproductive activity or reproductive problems" in claim 6 was indefinite. Applicants disagree. Applicants direct the Examiner to page 18, lines 23-27 of the specification, "female birds . . . can exhibit undesirable behavior as a result of reproductive activity or reproductive problems including excess vocalization . . . aggressiveness, biting, destruction of local environments. . . and feather mutilation." Applicants submit that the metes and bounds of the recitation "undesireable behavior as a result of reproductive activity or reproductive problems" are clear to one of skill in the art, as this recitation has been present in claim. Applicants note that this recitation was present in claim 6 prior to the issuance of the very first Office Action by the Patent Office (mailed July 14, 2003) and all the subsequent Office Actions, and is only now rejected. Applicants again express concern with failure to give full faith and credit to the search and actions of the previous Examiner and the piecemeal prosecution of the instant application.

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The Examiner also asserted that the recitation "wherein the immunoconjugate is dually functional" in claims 28 and 47 is indefinite, asserting "the two functions of the immunoconjugate are not recited. As such, what are the functions that the immunoconjugate comprises?" (page 4, Office Action mailed September 26, 2006). Applicants disagree and direct the Examiner to page 11, lines 24-31 of the specification; "[a] dually functional conjugate refers to a zona pellucida protein, or fragment thereof, conjugated to one independently protective carrier protein The carrier protein is advantageously selected to elicit immunological protection against an infection of disease state to which the intended subject may be exposed." Applicant's respectfully submit that the metes and bounds of the recitation "dually functional" are clear to one of skill in the art. Applicants note that the recitation "wherein the immunoconjugate is dually functional" was present in claim 28, as originally filed. Again, Applicants express concern with failure to give full faith and credit to the search and actions of the previous Examiner and the piecemeal prosecution of the instant application.

The Examiner asserted that the recitation "[a] method for affecting the reproductive system" in claim 29 is indefinite. Applicants note that this recitation was present in claim 29, as originally filed. Applicants note that this recitation was not rejected under 35 U.S.C. §112, second paragraph, in any of the previous, numerous, Office Actions. Applicants submit that this rejection is yet another example of piecemeal prosecution and of the newly assigned Examiner's failure to give full faith and credit to the search and actions of the previous Examiner and piecemeal prosecution. However, to expedite prosecution, claim 29 has been amended to recite "method for treating or preventing a reproductive disease, disorder, or condition related to egg production or egg laying in a bird." Reconsideration and withdrawal of this rejection is requested.

In view of the above discussion, reconsideration and withdrawal of the rejection of claims 4, 6, 12-15, 17-18, 21, 28, 29, and 42-47 under 35 U.S.C. §112, second paragraph, is requested.

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For: METHOD AND COMPOSITION FOR AFFECTING REPRODUCTIVE SYSTEMSClaim Objection

The Examiner objected to claims 23 and 41 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants submit that this objection is moot in view of the cancellation of claims 23 and 41.

The 35 U.S.C. §103/35 U.S.C. §112, first paragraph, "Squeeze"

Under 35 U.S.C. §103, "[t]he prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Likewise, "[a]ny analysis [under 35 U.S.C. §112, first paragraph,] of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention," and "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation" (see MPEP 2164.01). "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (see MPEP 2164.03).

Applicants respectfully submit that the Patent Office must apply a consistent interpretation of the knowledge in the state of the art as well as the predictability in the art when analyzing and rejecting claims under 35 U.S.C. §103 and 35 U.S.C. §112, first paragraph. Applicants submit that the Examiner has not done so in the instant case, rejecting the claimed methods as *prima facie* obvious over the prior art, asserting that there is a reasonable expectation of success with combining prior art teachings to obtain the claimed methods, yet rejecting the same claims as not enabled by the teachings of the specification combined with other knowledge available to the skilled artisan. Applicants submit that this is improper. Reconsideration and

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withdrawal of the rejections of the claims under 35 U.S.C. §103 and 35 U.S.C. §112, first paragraph, is requested.

The 35 U.S.C. §112 Rejection, first paragraph

The Examiner has newly rejected claims 4, 6, 12-15, 17-19, 21, 27-29, and 42-47 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. This rejection is traversed. Applicants respectfully submit that the specification provides adequate direction and guidance to enable one of skill in the art to make and use the claimed methods. Applicants direct the Examiner to, for example, Examples III, IV, and VIII (pages 22-24 and 27-28 of the specification) and Figures 2 and 3. Applicants submit that the enablement of the presently claimed methods has been repeatedly acknowledged by the U.S. Patent and Trademark Office during the prolonged prosecution of the present application.

The Examiner asserted that "[a]dministration of an immunogenic composition comprising avian and non-avian ZP proteins as per applicant's method elicits the production of antibodies that bind the ZP proteins present in the ovaries of the immunized bird. . . . The presence of these antibodies can have many effects, ranging from inhibition of sperm binding . . . to autoimmune-mediated destruction of ovarian tissue. . . . Given that the administration of ZP proteins to an animal often leads to ovarian autoimmune disease, it appears that applicant's method causes reproductive disease rather than prevents or treats reproductive diseases" (page 5, Office Action mailed September 26, 2006). Applicants disagree. Applicants submit that the specification teaches that the administration of immunogenic compositions of ZP induces immune responses that "can take the form of either immunocontraception or immunosterilization.

Immunosterilization means permanent, irreversible infertility, in contrast to immunocontraception wherein infertility is temporary or transient, and reversible.

Immunocontraception and immunofertilization are both dependent on the immune response to the subject, but *immunosterilization is typically the result of ovarian pathology caused by vaccine administration and high titers of anti-ZP antibodies*, as evidenced by, for example, total

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destruction of the zona pellucida proteins and/or influx of leukocytes into the follicles" (page 17, line 29 to page 30, line 4 of the specification (emphasis added)). Thus, Applicants submit that the development of ovarian pathology upon administration of an anti-ZP vaccine, as recognized by the teachings of Mahi-Brown et al., rather than support the non-enablement of the presently claimed methods, as asserted by the Examiner, establishes that one of skill in the art would have a reasonable expectation of success in practicing the claimed invention.

To support the assertion that the claimed methods are not enabled, the Examiner relies on the teachings of Mahi-Brown et al. (Birth Control Vaccines, 1995 pages 41-61), the very same teachings that the Examiner also relies on to assert that the presently claimed methods are obvious under 35 U.S.C. §103. Applicants do not understand this inconsistency. Applicants submit that Mahi-Brown et al. teach that "an antibody mediated-mechanism led to ovarian dysfunction and infertility," (see abstract of Mahi-Brown et al.) and thus the teachings of Mahi-Brown et al. support the enablement of the presently claimed methods.

The Examiner asserted that "the specification *prophetically* teaches that administering said composition [of avian and non-avian zona pellucida (ZP) protein] induces the production of antibodies . . . and that the presence of anti-ZP antibodies . . . [will] cause either temporary or permanent sterility. . . [t]herefore given . . . *the lack of a working example* comprising the administration of a composition comprising both avian and non-avian ZP proteins to a bird . . . , a skilled artisan would be unable to practice the breadth of applicant's claimed method without conducting undue research" (pages 5-6, Office Action mailed September 26, 2006). Applicants do not understand this position, in view of the Examiner's rejection of the claims under 35 U.S.C. §103, asserting that one of ordinary skill in the art would have a reasonable expectation of success in adding avian ZP proteins to non-avian ZP avian compositions administered to birds, to reduce or prevent fertility on birds (pages 6-7, Office Action mailed September 26, 2006).

The Examiner asserted that "[p]revention requires that the applicant's claimed method works in 100% of animals 100% of the time" (page 5, Office Action mailed September 26, 2006). Applicants disagree and respectfully request that the Examiner substantiate this assertion.

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In view of the above discussion, reconsideration and withdrawal of this rejection of the claims under 35 U.S.C. §112, first paragraph, is requested.

35 U.S.C. §103 Rejections

The Examiner rejected claims 4, 6, 12-15, 17, 18, 21, 27-29, 42, and 44-47 under 35 U.S.C. §103(a) as being unpatentable over Curtiss et al. (U.S. Patent 5,656,488) in view of Harris et al. (U.S. Patent 5,976,545) in view of Mahi-Brown et al. (Birth Control Vaccines, 1995, pages 41-61) and in view of Waclawek et al. (Biology of Reproduction, 1998, 59:1230-1239). This rejection is traversed. Applicants submit that one of skill in the art would have had no motivation to combine the teachings of Curtiss et al. in view of Harris et al. in view of Mahi-Brown et al. and in view of Waclawek et al. In fact, Applicants submit that the teachings Curtiss et al., Harris et al., Mahi-Brown et al., and Waclawek et al. teach away from combining the teachings Curtiss et al., Harris et al., Mahi-Brown et al., and Waclawek et al.

The Examiner cited Curtiss et al. as "teach[ing] reducing or preventing fertilization of eggs in birds by administering a glycoprotein, ZP3, from pigs" and that Curtiss et al. "do not teach administering a composition comprising non-avian and avian ZP to a bird." Harris et al. is cited as teaching "that the ZP proteins administered to an animal must be capable of eliciting an antibody response that reacts with the animal's endogenous ZP proteins to be therapeutically effective." Mahi-Brown et al. is cited as teaching "that administered *ZP proteins are not immunogenic when administered to the same species*" (emphasis added). And, Waclawek et al. is cited as teaching "the purification and protein sequence of chicken ZP3" (page 7, Office Action mailed September 26, 2006).

The Examiner asserted that it would have been obvious . . . to add avian ZP proteins to the compositions administered to birds in the methods taught by Curtiss et al. (page 7, Office Action mailed September 26, 2006). Applicants respectfully disagree. In fact, Applicants submit that the cited teachings of Mahi-Brown et al. teach away from adding avian ZP-protein to the composition taught by Curtiss et al.

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The Examiner asserted that the "[m]otivation to do so comes from the teachings of Harris et al. that elicited antibody responses must be capable of crossreacting with endogenous ZP protein and the teachings of Mahi-Brown that endogenous ZP proteins are not immunogenic As such, the presence of porcine ZP protein . . . would assure that an immune response was generated *while the presence of the avian ZP protein would ensure that some of the elicited response was directed to endogenous avian ZP proteins*" (pages 7-8, Office Action mailed September 26, 2006). Applicants respectfully disagree. Applicants submit that none of the cited teachings provide motivation to add non-avian ZP to a composition for administration to a bird. Applicants submit that none of the cited teachings teach that "*the presence of the avian ZP protein would ensure that some of the elicited response was directed to endogenous avian ZP proteins*" as asserted by the Examiner. Further, Applicants submit that this assertion makes no sense in view of the Examiner's reliance on the teachings of Mahi-Brown et al., "that administered *ZP proteins are not immunogenic when administered to the same species*" (page 7, Office Action mailed September 26, 2006 (emphasis added)).

Reconsideration and withdrawal of the rejection of claims 4, 6, 12-15, 17, 18, 21, 27-29, 42, and 44-47 under 35 U.S.C. §103(a) as being unpatentable over Curtiss et al. in view of Harris et al. in view of Mahi-Brown et al. and in view of Wacławek et al.

The Examiner rejected claims 19 and 43 as being unpatentable over Curtis et al. in view of Harris et al. in view of Mahi-Brown et al. and in view of Wacławek et al. as applied to claims 4, 6, 12-15, 17, 18, 21, 27-29, 42 and 44-47, and further in view of Willis et al. (J. Equine Vet Sci., 1994, 14:364-370). This rejection is traversed. For the reasons discussed in the above section addressing the rejections of the claim 4, 6, 12-15, 17, 18, 21, 27-29, 42, and 44-47 under 35 U.S.C. §103, Applicants submit that Curtis et al. in view of Harris et al. in view of Mahi-Brown et al. and in view of Wacławek et al. do not make obvious the methods of claims 4, 6, 12-15, 17, 18, 21, 27-29, 42 and 44-47. Applicants submit that the deficiencies in the teachings of Curtis et al. in view of Harris et al. in view of Mahi-Brown et al. and in view of Wacławek et al. are not corrected by combination with the teachings of Willis et al. Accordingly, Applicants

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respectfully request reconsideration and withdrawal of the rejections of claims 19 and 43 under 35 U.S.C. §103(a).

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It is respectfully submitted that the pending claims 4, 6, 12-15, 17-19, 21, 27-29 and 42-47 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 26 day of February, 2007, at 2:55pm (Central Time).

By: Sandy TruehartName: Sandy Truehart